IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ulrike SCHULZ et al.

Confirmation No.: 2144
Group Art Unit: 1613

Serial No. : 10/574,231

Examiner: Lea, Christopher Raymond

I. A. Filed : March 10, 2005

For : TRANSPARENT COSMETIC OR DERMATOLOGICAL FORMULATION

(SECOND) APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
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Alexandria, VA 22314

Sir:

This Appeal is from the Examiner's Final Rejection of claims 34-57 set forth in the Final Office Action mailed from the U.S. Patent and Trademark Office on February 18, 2011.

A Notice of Appeal in response to the February 18, 2011 Final Office Action was filed on June 17, 2011. A request for a one-month extension of time is being filed concurrently herewith.

The fee for filing an Appeal Brief in support of a Notice of Appeal set forth in 37 C.F.R. § 41.20(b) was paid on March 29, 2010 when the first Appeal Brief was filed. Pursuant to MPEP 1204.01 the U.S. Patent and Trademark Office is hereby authorized to charge the difference between the current fee for an Appeal Brief and the fee effective on March 29, 2010, if any, as well as any additional fees which may be deemed necessary for entering the present Appeal Brief to Deposit Account No. 19-0089. The fee for a one-month extension of time is being paid concurrently herewith.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Beiersdorf AG of Hamburg, Germany. The corresponding assignment was recorded in the U.S. Patent and Trademark Office on August 31, 2006 at REEL 018243, FRAME 0908.

II. RELATED APPEALS AND INTERFERENCES

An Appeal Brief was filed on April 8, 2011 and a Reply Brief was filed on July 26, 2011 in related co-pending Application No. 11/586,585. An Appeal Brief was filed in related co-pending Application No. 10/574,219 on June 13, 2011. Appellants, Appellants' representative or the Assignee are not aware of any other prior and pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Claims 34-57 are pending in this application.

Claims 1-33 are cancelled.

Each of claims 34-57 is indicated as rejected in the Final Office Action mailed February 18, 2011.

The rejection of each of claims 34-57 is under appeal. Claims 34-57 involved in the appeal are reproduced in the Claims Appendix attached hereto.

IV. STATUS OF AMENDMENTS

No Amendment has been filed subsequent to the Final Office Action mailed February 18, 2011.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 34

Independent claim 34 is drawn to a cosmetic or dermatological formulation which is transparent and comprises (a) at least one antiperspirant active ingredient, (b) mandelic acid and (c) water. Components (a), (b) and (c) are present in ratios which result in gelling.

See, e.g., page 9, lines 12-14 and 20-27 and page 10, lines 3-7 of the present specification.

B. Claim 49

Independent claim 49 is drawn to a cosmetic or dermatological antiperspirant formulation which is free from zirconium containing antiperspirant active ingredients and transparent. The formulation comprises (a) an antiperspirant active ingredient which comprises one or more aluminum salts, (b) at least one α-hydroxycarboxylic acid and (c) water. Components (a), (b) and (c) are present in ratios which result in gelling.

See, e.g., page 9, lines 12-14 and 20-27 and page 10, lines 3-5 of the present specification.

C. Claim 55

Independent claim 55 is drawn to a cosmetic or dermatological antiperspirant formulation which is transparent and suitable for application to human skin. The formulation comprises (a) from 1% to 20% by weight of an antiperspirant active ingredient which comprises one or both of an aluminum salt and an aluminum zirconium salt, (b) from 0.1% to 8% by weight of mandelic acid and (c) water. Components (a), (b) and (c) are present in ratios which result in gelling.

See, e.g., page 9, lines 12-14 and 20-27 and page 10, lines 3-10, 14-21 and 24-25 of the present specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The broad issues under consideration are:

1. Whether claims 49, 50 and 53 are properly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Williams et al., GB 2280111 (hereafter "WILLIAMS").

2. Whether claims 34-57 are properly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Guskey et al., U.S. Patent No. 5,776,494 (hereafter "GUSKEY") in view of Bhakoo et al., US 2003/0059396 A1 (hereafter "BHAKOO") and Hei et al., U.S. Patent No. 6,593,283 (hereafter "HEI"), and in particular, whether the disclosures of GUSKEY, BHAKOO and HEI are sufficient to establish a *prima facie* case of obviousness of the subject matter of claims 34-57.

Appellants further point out that the provisional rejections on the ground of nonstatutory obviousness-type double patenting based on co-pending application Nos.

10/574,219, 10/574,230 and 11/586,585 also set forth in the February 18, 2011 Final Office Action are not presented for review. Appellants will decide whether the submission of one or more terminal disclaimers is appropriate once allowable subject matter has been indicated in the instant application and in the co-pending applications.

VII. ARGUMENTS

A. Citation of Authority

1. Anticipation

Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art to show each and every limitation of a claimed invention. *Celeritas Technologies, Ltd. v. Rockwell International Corporation*, 150 F.3d 1354, 1360, 47 USPQ 2d 1516, 1522 (Fed. Cir. 1998); *Oakley, Inc. v. Sunglass Hut International,* 65 USPQ2d 1321, 1325 (Fed. Cir. 2003); *Applied Medical Resources Corporation v. United States Surgical Corporation*, 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998); *Rockwell International Corporation v. The United States, et al.*,147 F.3d 1358, 47 USPQ2d 1027, 1029 (Fed. Cir. 1998).

An "anticipating" reference must describe all of the elements and limitations of the claim as arranged in the claim in a single reference, and enable one of skill in the field of the invention to make and use the claimed invention. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc*., 246 F.3d 1368, 1378-79 (Fed. Cir. 2001); *Richardson v. Suzuki Motor Co*., 868 F.2d 1226 (Fed. Cir. 1989); *Merck & Co., Inc., v. Teva Pharmaceuticals USA, Inc.* 347 F.3d 1367 (Fed. Cir. 2003); *NetMoneyIN, Inc. v. VeriSign, Inc.,* 545 F.3d 1359 (Fed. Cir. 2008).

A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim. *EMI Group N. Am., Inc., v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001); *Schering Corp. v. Geneva Pharm.,* 339 F.3d 1373, 1379 (Fed. Cir. 2003).

If a reference does not expressly set forth a particular element of a claim, that reference may still anticipate the claim if the element is "inherent" from the reference. Matter is "inherent" if the extrinsic evidence makes it clear that the matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002); *In re Crish*, 393 F.3d 1253, 1258-59 (Fed. Cir. 2004). Inherency, however, cannot arise from probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. To the contrary, a certain thing must result from a given set of circumstances to be inherent. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

"[T]he statute provides for what may be said to be a presumption of novelty in the language of section 102 'a person shall be entitled to a patent unless ---' (Emphasis added). What this means, in an *ex parte* proceeding to obtain a patent, is that the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." *In re Wilder,* 429 F.2d 447, 450 (CCPA 1970).

2. Obviousness

The appropriate starting point for a determination of obviousness is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 466 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

"A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The relevant question is "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* "We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512, F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d, 1531, 1532 (Fed. Cir. 1993), citing *In re Fine*, 837 F.2d 1071, 1074,5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), quoted with approval in *KSR Int'l Co. v. Teleflex Inc., supra.*

"[I]t is not enough to simply show that the references disclose the claim limitations; in addition, 'it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.'" *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617, F.3d 1296, 1303 (Fed. Cir. 2010) (quoting *KSR Int'l Co. v. Teleflex Inc., supra).*

Ultimately therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir 1995). Further, it is also necessary for the Examiner to properly construe what an applied reference *fairly* teaches or discloses. See, e.g., *In re Fracalossi and Wajer*, 681 F.2d 792 (CCPA 1982).

B. Claims 49, 50 And 53 Are Not Properly Rejected Under 35 U.S.C. 102(b) As Being Anticipated By WILLIAMS

1. Summary of Rejection

The rejection specifically relies upon Example 9 of WILLIAMS and alleges that this Example discloses a clear gel containing 20% aluminum chlorohydrex (which allegedly is a combination of aluminum chlorohydrate and propylene glycol), 0.5% lactic acid and water. The rejection further alleges that "[s]ince the composition is taught as a gel, the antiperspirant, acid, and water are present in a ratio that resulted in gelling."

2. Traverse

Appellants submit that the Examiner's allegation that merely because Example 9 of WILLIAMS describes the composition as containing the three components recited in claim 49 and also describes the composition as being a gel clearly does not mean, let alone necessarily mean, that the three components recited in claim 49 are present in ratios which result in gelling.

For example, that the composition of Example 9 of WILLIAMS is described to be a gel can reasonably be explained by the fact that the composition contains 3 % by weight of dibenzylidene sorbitol, i.e., a substance which is expressly mentioned in WILLIAMS as the preferred gelling agent for use in the clear gel antiperspirant compositions of WILLIAMS. In other words, due to the presence of a gelling agent it is reasonable to assume that the composition of Example 9 of WILLIAMS would be a gel even if aluminum chlorohydrex, lactic acid and water are present therein in ratios which (alone) do not result in gelling.

In this regard, the following passages of WILLIAMS deserve particular attention (emphasis added):

> Clear gel antiperspirant compositions comprise an antiperspirant active, a dihydric alcohol as primary solvent, a cosolvent of polyethylene glycol, water, and/or glycerine, a buffering agent, and a gelling agent. The antiperspirant active is e.g. an aluminium salt or an aluminium and/or zirconium complex. Typical dihydric alcohol components are di or propylene glycol, hexylene glycol and/or pentanediol.

Abstract.

> Water can be included in the composition as an alternate or additional cosolvent. Water functions to prevent syneresis or sweating of the composition on exposure to air. In addition, water can also be used to give the composition a dry feel as opposed to a sticky feel. When water is present in the composition, there must be sufficient gelling agent to cause the composition to solidify at a

temperature of less than or equal to about 90°C so that the water does not boil off during processing.

The amount of water used should be between about 1% and 20% by weight of the composition. In a preferred embodiment, the amount of water is between about 3% and 15% by weight of the composition; in a more preferred embodiment, the amount of water is between about 5% and 15% by weight; and, in an even more preferred embodiment, the amount of water is between about 5% and 13% by weight.

Page 5, line 25 to page 6, line 8.

A buffering agent or system is used in the composition of the invention to prevent wide pH swings.

Ideally, the buffering agent is an acid/base system having a pK_a of from about 3.5 to about 5, preferably from about 4.5 to about 5.

The buffering agent is selected from phosphate buffers such as sodium or potassium phosphate, phosphoric acid, potassium hydroxide, potassium acid phthalate, triethanolamine, citric acid, sodium citrate, aluminium lactate, lactic acid and mixtures thereof. In a preferred embodiment, a buffer solution of citric acid, sodium citrate and potassium hydroxide is used.

In general, an inorganic buffering agent is more heat stable. However, phosphate buffers, for example, increase the amount of salting or grittiness that occurs on standing due to breakdown of the antiperspirant active salt into insoluble components.

The greater the amount of buffering agent in the composition, the better the stability of the composition and the better the pH is controlled. On the other hand, lower amounts of buffering agents are preferred in order to increase the clarity of the solution and decrease the formation of insoluble components.

The buffering agent is generally present in an amount between about 0.1% and 3% by weight of the composition of the invention. In a preferred embodiment, the buffering agent is present in an amount between about 0.2% and 2% by weight of the composition and in an especially preferred embodiment, the buffering agent is present in an amount between about 0.2% and 1% by weight.

Page 6, line 19 to page 7, line 14.

A material that functions as a gelling agent at a low pH and at high temperatures of up to about 140° C is also present in the composition. The gelling agent is preferably selected from dibenzylidene sorbitol resin, derivatives of dibenzylidene sorbitol resin, and mixtures thereof. In a preferred embodiment, the gelling agent is dibenzylidene sorbitol resin.

In general, dibenzylidene sorbitol resin and its derivatives degrade or decompose under acidic conditions, specifically at a pH of less than about 7, and at high temperatures to form sorbitol and benzaldehyde. This decomposition can be confirmed by the presence of benzaldehyde, which has a characteristic sweet odour

> that is reminiscent of freshly crushed bitter almonds. However, the presence of the buffering agent in the composition of the invention slows the degradation of the dibenzylidene sorbitol resin considerably, thereby permitting the composition to have little or no almond odour, which is considered acceptable.
>
> The gelling agent is preferably present in an amount between about 1% and 5% by weight of the composition. In a preferred embodiment, the gelling agent is present in an amount between about 2% and 4% of the composition.

Page 7, lines 15-34.

None of the above passages of WILLIAMS provides the slightest indication that in the compositions of WILLIAMS (i) water, if present at all, has a function other than to prevent syneresis or sweating of the composition on exposure to air and to give the composition a dry feel as opposed to a sticky feel, (ii) lactic acid has any function other than to buffer the composition and (iii) the employment of a gelling agent such as dibenzylidene sorbitol is not necessary for the composition to form a gel.

It further is to be taken into account here that the amount of water in the composition of Example 9 of WILLIAMS, i.e., about 5 % by weight, is relatively small, which is yet another reason why there is no reasonable basis for believing that the composition of Example 9 of WILLIAMS would have gelled in the absence of dibenzylidene sorbitol. For example, in comparison, all of the compositions which are exemplified in the instant specification comprise at least 87 % by weight of water, which is much more than the two remaining components recited in instant claim 49.

In view of at least all of the foregoing facts it is apparent that there is no basis whatsoever for the assumption that the composition of Example 9 would have been a gel even without the presence of 3 % by weight of dibenzylidene sorbitol therein. Further, the fact that the composition of Example 9 of WILLIAMS contains a substance which is described therein as a (preferred) gelling agent is a strong indication that the composition

would not have been a gel in the absence of this gelling agent. Otherwise there would not have been any good reason for the incorporation of a gelling agent into the composition of Example 9.

Accordingly, the Examiner's allegation that in the composition of Example 9 of WILLIAMS aluminum chlorohydrate, lactic acid and water (necessarily) are present in ratios which result in gelling is nothing more than a speculation that is not supported by any evidence whatsoever. In this regard, Appellants point out that "the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to Applicants to disprove the inherency. *Ex parte Skinner,* 2 USPQ2d 1788, 1789 (BPAI 1986). "[T]he statute provides for what may be said to be a presumption of novelty in the language of section 102 'a person shall be entitled to a patent unless ---' (Emphasis added). What this means, in an *ex parte* proceeding to obtain a patent, is that the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." *In re Wilder,* 429 F.2d 447, 450 (CCPA 1970).

Appellants note that in response to the above arguments, the Examiner takes the position that the composition of Example 9 of WILLIAMS and the claimed cosmetic or dermatological formulation contain the same ingredients and are present as a gel, wherefore they allegedly are (necessarily) the same and have the same properties. In this regard, it is pointed out that the Examiner has not identified any composition of WILLIAMS that contains components (a), (b) and (c) recited in the rejected claims in concentrations and ratios at least similar to those exemplified in the present specification

and would thus, make it reasonable to assume that the composition of Example 9 or any other Example of WILLIAMS contains components (a), (b) and (c) in ratios which result in gelling (without use of a separate gelling agent).

Appellants further note that the Examiner maintains the position that the phrase "(a), (b) and (c) being present in ratios which result in gelling" recited in claim 49 does not mean that the ratios of (a), (b) and (c) must cause the composition to gel but merely requires that the composition is present as a gel, regardless of whether or not the ratios of (a), (b) and (c) by themselves cause the composition to be a gel.

In this regard, it is pointed out that the claims of a patent (application) are to be construed as one of ordinary skill in the art would understand them. Appellants submit that one of ordinary skill in the art would understand the instant claims to mean that even in the absence of any additional gelling agents components (a), (b) and (c) by themselves result in (are responsible for, cause, etc.) a gelling of the composition. Appellants further note that "[a]lthough the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach." *In re Cortright, 1*65 F.3d 1353, 1358 (Fed. Cir. 1999). See also *In re Morris,* 127 F.3d 1048, 1054 (Fed. Cir. 1997) ("[I]t would be unreasonable for the PTO to ignore any interpretative guidance afforded by applicant's written description."). The Examiner must therefore "determine[] the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'" *Phillips v. AWH Corp. , 415* F.3d 1303, 1316 (Fed. Cir. 2005).

In other words, one of ordinary skill in the art taking into consideration the instant specification would inevitably arrive at the conclusion that claim 49 recites that components (a), (b) and (c) are present in ratios which *per se* result (are responsible for, cause, etc.) a gelling of the composition, i.e., even if no separate gelling agent is added.

It additionally is noted that if the Examiner's construction of the instant claims were correct, i.e., that any ratio of (a), (b) and (c) is considered to result in gelling if the composition is present as a gel (even if a separate gelling agent is required for making the composition gel), the phrase "(a), (b) and (c) being present in ratios which result in gelling" in instant independent claim 49 becomes meaningless. Claim language, however, "should not [be] treated as meaningless." *Bicon, Inc. v. Straumann Co.,* 441 F.3d 945, 951 (Fed. Cir. 2006). Claims are construed with an eye toward giving effect to all terms in the claim. *Bicon Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). See also *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (denouncing claim constructions which render phrases in claims superfluous). Further, "[c]laims are not to be read in a vacuum[;] while it is true they are to be given the broadest reasonable interpretation during prosecution, their terms still have to be given the meaning called for by the specification of which they form a part." *In re Royka*, 490 F.2d 981, 984 (CCPA 1974).

Further, if the Examiner's construction of claim 49 were correct, the phrase "(a), (b) and (c) being present in ratios which result in gelling" could (and should) have been replaced by "the formulation being present as a gel" or a similar phrase. In fact, in this case the Examiner should have rejected claim 49 as indefinite because it does not become

sufficiently clear therefrom whether or not the ratios of (a), (b) and (c) must play a role in the formation of a gel.

Appellants submit that for at least all of the foregoing reasons, the instant rejection under 35 U.S.C. § 102(b) is without merit and should be reversed, which action is respectfully requested.

C. Claims 34-57 Are Not Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over GUSKEY In View of BHAKOO And HEI

1. Summary of Rejection

The rejection essentially alleges that GUSKEY teaches a topical pharmaceutical composition comprising at least one active agent, a gelling agent, and an anhydrous solvent and that among the active agents, aluminum and aluminum-zirconium chlorohydrate and mandelic acid are mentioned. The rejection also notes that although GUSKEY teaches that an anhydrous solvent is used, GUSKEY also teaches that the anhydrous solvent may contain up to 5 % of water. The rejection concedes that "Guskey et al. do not exemplify an embodiment that contains the specific active agents in the claimed ratios" but essentially alleges that this deficiency of GUSKEY is cured by BHAKOO and HEI.

2. Traverse

a. GUSKEY fails to provide an apparent reason for the employment of water (in an amount which results in gelling)

Appellants point out that all of the instant independent claims recite, *inter alia*, that antiperspirant active agent, α-hydroxycarboxylic acid (mandelic acid) and water are present in ratios which result in gelling.

In contrast, GUSKEY fails to teach or suggest that water is an essential component of the pharmaceutical compositions disclosed therein, let alone that water needs to be present in a concentration - relative to the concentrations of antiperspirant active agent and α-hydroxycarboxylic acid - which results in the formation of a gel. In this regard, it further is pointed out that even if one were to assume, *arguendo*, that the concentration of water in the compositions of GUSKEY can be unlimited, there would be no reason, let alone an apparent reason for one of ordinary skill in the art to adjust the amount of water with respect to antiperspirant active agent and α-hydroxycarboxylic acid so that the ratio of these three components results in gelling because the compositions of GUSKEY already contain a gelling agent.

At any rate, GUSKEY teaches that water not only is not an essential component of the pharmaceutical compositions disclosed therein but even makes is clear that the presence of water in these compositions is undesirable and should be avoided to the greatest possible extent, thereby even discouraging the presence of water in the compositions of GUSKEY.

For example, component C of the compositions of GUSKEY (in addition to at least one pharmaceutical active A and a specific type of gelling agent B) is an anhydrous liquid carrier. See, e.g., independent claims 1 and 19 of GUSKEY. In this regard, GUSKEY states in col. 10, lines 21-35 thereof (emphasis added):

> The anhydrous liquid carrier preferably comprises one or more anhydrous liquids suitable for topical application to human skin, which carrier or combination of liquid carriers are liquid under ambient conditions. The term "anhydrous" as used herein means that the pharmaceutical gel compositions of the present invention, and the essential or optional components thereof other than the pharmaceutically acceptable actives, are substantially free of added or free water. From a formulation standpoint, this means that the pharmaceutical gel compositions of the present invention preferably contain less than about 5%,

> preferably less than about 3%, more preferably less than about 1%, most preferably zero percent, by weight of free or added water, other than the water of hydration typically associated with the pharmaceutically acceptable actives prior to formulation.

Accordingly, even if GUSKEY indicates that the presence of (unintentionally present) small amounts of water in the compositions disclosed therein can be tolerated, GUSKEY nevertheless provides a clear teaching that water is most preferably (completely) absent from these compositions. It is not seen that this prompts one of ordinary skill in the art to intentionally employ water in any amount, let alone to employ water in an amount which results in a ratio with respect to antiperspirant active agent and α-hydroxycarboxylic acid that results in gelling (as pointed out above, the compositions of GUSKEY must contain a (specific) gelling agent, anyway).

Appellants point out that GUSKEY unambiguously states that the pharmaceutical gel compositions taught therein "preferably contain less than about 5%, preferably less than about 3%, more preferably less than about 1%, most preferably zero percent, by weight of free or added water, other than the water of hydration typically associated with the pharmaceutically acceptable actives prior to formulation", thereby clearly discouraging the use of water in any amount in the compositions disclosed therein or, at the very least, failing to provide any apparent reason for one of ordinary skill in the art to provide compositions according to GUSKEY which contain more than insignificant or not reasonably avoidable amounts of water.

In this regard, it is noted that the question here is not even whether GUSKEY discourages, or teaches away from, the use of water in the compositions disclosed therein but rather is whether GUSKEY would have prompted one of ordinary skill in the art to use water in these compositions (e.g., to add water to a substantially anhydrous

composition according to GUSKEY). The latter can clearly be answered in the negative, taking into account that according to GUSKEY "the pharmaceutical gel compositions of the present invention preferably contain .... most preferably zero percent, by weight of free or added water". Appellants note that it is necessary for the Examiner to properly construe what an applied reference *fairly* teaches or discloses. See, e.g., *In re Fracalossi and Wajer*, 681 F.2d 792 (CCPA 1982).

It further is pointed out again that the compositions of GUSKEY contain a gelling agent, i.e., an agent whose very purpose is to cause (result in) the formation of a gel, wherefore the question arises what would motivate one of ordinary skill in the art to adjust the ratio of antiperspirant active ingredient, α-hydroxycarboxylic acid and water (assuming, *arguendo*, all of these components can reasonably be expected to be present at the same time in a composition according to GUSKEY) to result in gelling, i.e., to independently form a gel by themselves, in addition to the gel already formed by the gelling agent (if possible at all). In this regard, Appellants note that "[i]n rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d, 1531, 1532 (Fed. Cir. 1993), citing *In re Fine*, 837 F.2d 1071, 1074,5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

Appellants further note that the Examiner essentially takes the position that the instant claims do not require that the ratios of components (a), (b) and (c) by themselves (i.e., without presence of additional gelling agent) cause gelling of the composition but

only require that components (a), (b) and (c) are present and, independently, the composition is present as a gel.

It is submitted that for at least all of the reasons which are set forth above in section VII.B.2., the Examiner clearly has misconstrued the present claims. Independent claims 34, 49 and 55 unambiguously recite (and are understood by one of ordinary skill in the art to mean) that water is present in a ratio with respect to (a) at least one antiperspirant active ingredient and (b) α-hydroxycarboxylic acid (mandelic acid) that results in gelling, i.e., these claims (especially when read in light of the specification) leave absolutely no doubt that it is not sufficient for components (a), (b) and (c) to merely be comprised in a composition that is present in the form of a gel, but that on the contrary, the ratios of (a), (b) and (c) must be such that even in the absence of a (separate) gelling agent a gel is formed.

b. GUSKEY fails to teach or suggest the simultaneous use of antiperspirant active ingredient and α-hydroxycarboxylic acid (and water)

Appellants further point out that GUSKEY mentions aluminum or aluminum-zirconium chlorohydrate and mandelic acid only as two examples of the many types of active agents which may be present in the compositions disclosed therein (i.e., antiseptic or antibacterial actives, antifungal agents, hormones, exfoliating agents, topical analgesics, sunscreen actives, antidandruff agents, antioxidants and vitamins, to name but a few). Accordingly, there is an almost unlimited number of possible combinations of active agents that is encompassed by the disclosure of GUSKEY, and nothing in GUSKEY teaches or suggests that a combination of aluminum or aluminum-zirconium

chlorohydrate and mandelic acid (or any other hydroxycarboxylic acid) is associated with any benefit. In this regard, it is noted that the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

In addition, mandelic acid is mentioned in GUSKEY as an example of an exfoliating agent whereas aluminum and aluminum-zirconium chlorohydrates are mentioned in GUSKEY as examples of antiperspirant actives which may be present in the compositions taught therein (see col. 5, lines 34-50 and col. 7, lines 40-47 of GUSKEY).

It is not seen that there is any relationship between an exfoliating agent and an antiperspirant active, let alone a relationship which would make the simultaneous use thereof appear expedient and desirable. In other words, it is not seen that one of ordinary skill in the art has an apparent reason to include an antiperspirant active in a composition for exfoliating the skin or to include an exfoliating agent in an antiperspirant composition. After all, someone using an antiperspirant composition on the skin does not usually wish the skin to exfoliate there, and neither would someone be interested in an exfoliant that has antiperspirant properties as well. In addition, an antiperspirant is effective only as long as it is present on the skin, whereas an exfoliant is not generally supposed to stay on the skin for extended periods similar to those used for conventional antiperspirants but is rinsed off once it has served its purpose. In view thereof, it would not make sense to add an antiperspirant to an exfoliant and it may even be harmful (especially to sensitive skin, e.g., in the armpits which is a typical place for the application of an antiperspirant) to add an (acidic) exfoliant to an antiperspirant

composition. In this regard, it is pointed out that the Examiner has failed to provide any evidence which would contradict these statements, and in particular has not provided any evidence whatsoever which could be considered to support an allegation that it is not unusual for antiperspirants to contain exfoliating agents and/or for exfoliating agents to contain antiperspirants.

Accordingly, there is no apparent reason for one of ordinary skill in the art to provide a composition in accordance with the teaching of GUSKEY that comprises (i) an exfoliating agent and in particular, an α-hydroxycarboxylic acid such as, e.g., mandelic acid, (ii) an antiperspirant active (and (iii) water), let alone in relative ratios which result in a gelling of the composition.

c. GUSKEY fails to teach or suggest that the compositions taught therein are or should be transparent

All of the instant independent claims recite, *inter alia*, that the claimed formulation is transparent. The Examiner does not appear to offer any comment in this regard.

d. BHAKOO and HEI are unable to cure the noted deficiencies of GUSKEY

BHAKOO and HEI are unable to cure any of the deficiencies of GUSKEY set forth above. In this regard, it is noted that the Examiner has failed to provide any explanation whatsoever as to why BHAKOO and HEI would allegedly have cured the deficiencies of GUSKEY set forth above in subparagraphs a. and c.

Regarding the deficiency of GUSKEY set forth above in subparagraph b. Appellants point out that BHAKOO explicitly teaches in paragraphs [0006] and [0007] thereof that the antimicrobial benefit and subsequent malodor reduction obtained with typical antimicrobial agents that are used as deodorants, particularly many hours after application, "is not always excellent" and that the inventors of BHAKOO have discovered synergistic mixtures of picolinic acid and a peroxyl species or equivalent source thereof that can achieve the target of providing an excellent antimicrobial benefit and subsequent malodor reduction. BHAKOO does not appear to mention mandelic acid, i.e., not even as an antimicrobial agent which is comparable with the typical antimicrobial agents which are used as deodorants.

HEI merely teaches antimicrobial compositions which contain antimicrobially active solvents as set forth in col. 7, lines 1-45 thereof and preferably contain an (optional) additional antimicrobial agent which can be dissolved or dispersed in the antimicrobially-active solvent or in the diluting solvent (col. 10, lines 22-25). Mandelic acid is included in a laundry list of specific compounds and types of compounds of most diverse structures which may be used as additional antimicrobial agent. According to the paragraph bridging columns 10 and 11 of HEI compositions which contain "such optional additional antimicrobial agents appear to have substantially greater antimicrobial effectiveness than comparison aqueous solutions or dispersions containing the additional antimicrobial agent [i.e., the antimicrobially active solvent] alone."

In other words, HEI makes it clear that if used alone, compounds such as, e.g., mandelic acid are not particularly effective as antimicrobial agents, and HEI fails to teach or suggest that mandelic acid by itself would be useful as deodorant.

It further is pointed out that although HEI discloses a large number and variety of potential uses for the antimicrobial compositions disclosed therein (see col. 11, line 58 to col. 13, line 32) the application of these compositions to human skin is not taught or suggested. The closest disclosure in this regard appears to be in col. 12, lines 28-30 of HEI where it is stated that "[t]he antimicrobial compositions of the invention can be used for treating skin diseases on animals (especially mammals)".

In this regard, it also must not be forgotten that mandelic acid is mentioned in GUSKEY as an example of an exfoliating agent. Accordingly, even if one were to assume, *arguendo*, that HEI teaches that mandelic acid has deodorizing properties (which HEI fails to do), the fact that mandelic acid also has exfoliating properties would clearly be a disincentive rather than a motivation to employ it in an antiperspirant composition. (Neither has the Examiner provided any evidence which would support an allegation that antiperspirants usually contain exfoliating agents.) This disincentive is not alleviated or "neutralized" by the disclosure of HEI because HEI fails to teach the application of the compositions disclosed therein to human skin (let alone for deodorizing purposes).

Appellants note that in this regard the Examiner points to col. 12 of HEI where it is stated that skin diseases include athlete's foot (a disease that allegedly afflicts (only) humans) and where it is also stated that the compositions of HEI can be used, *inter alia*, as hand soaps and pre-or post-surgical scrubs.

However, it is apparent that hand soaps and pre-or post-surgical scrubs come into contact with human skin only temporarily, i.e., only for short periods of time, in contrast to an antiperspirant composition according to GUSKEY. Further, athlete's foot (which may arguably require prolonged contact of the active agent with the skin) apparently is a

condition that can affect animals as well. In particular, HEI states in col. 12, lines 28-41 (emphasis added):

> The antimicrobial compositions of the invention can be used for treating skin diseases on animals (especially mammals), or those which spread via transfer to air or surface substrates, such as disease from fungi, molds, bacteria spores and viruses. These spreadable skin diseases include athletes foot fungus and hairy hoof wart disease, and the many organisms leading to Mastitis and other mammalian milking diseases. The disease can be a viral disease such as parvovirus, coxsackie virus, or herpes virus. The disease can also be bacterial, such as S. aureus, E. coli, Streptococci, etc., or a Mycobacterium type such as that leading to tuberculosis. The compositions may also be used to treat animal carcasses to reduce both pathogenic and non-pathogenic microbial levels.

The above passage of HEI leaves no doubt that the "athletes foot fungus" mentioned therein is meant to affect animal skin (just like the hairy hoof wart disease, mastitis and mammalian milking diseases mentioned in the same sentence).

In view of the foregoing, it is submitted that BHAKOO and HEI fail to render it obvious (i.e., provide an apparent reason) to one of ordinary skill in the art to include mandelic acid in a composition according to GUSKEY that contains aluminum or aluminum-zirconium chlorohydrate as antiperspirant active agent.

Appellants submit that for at least all of the foregoing reasons, the Examiner has failed to establish a prima facie case of obviousness of the subject matter of any of the instant claims over a combination of GUSKEY, BHAKOO and HEI.

d. Additional reasons why GUSKEY BHAKOO and HEI fail to render obvious specific claims (i.e., claims which do not stand or fall together with the remaining claims)

Instant claims 38-40 recite various ratios of the at least one antiperspirant active ingredient and mandelic acid in the formulation of claim 34. Appellants note that in this

regard the Examiner merely relies on the fact that GUSKEY mentions that the active agents in the composition taught therein are present in a safe and effective amount, wherefore one of ordinary skill in the art would allegedly arrive at the ratios recited in claims 38-40 empirically. Page 5, first paragraph of the February 18, 2011 Final Office Action.

Appellants fail to see that the use of safe and effective amounts of antiperspirant active ingredient and mandelic acid (if used together) in a composition according to GUSKEY would automatically result in a ratio within the ranges recited in claims 38-40. It further has to be taken into account here that the ratio of these components and water together additionally have to result in gelling. GUSKEY is completely silent in this regard.

The above arguments equally apply to claim 56 (which depends from claim 55).

Instant claims 41-45 recite various concentration ranges for the at least on antiperspirant active ingredient and mandelic acid in the formulation of claim 34. Appellants note that in this regard the Examiner merely relies on the fact that GUSKEY mentions that the active agents in the composition taught therein are present in a safe and effective amount, wherefore one of ordinary skill in the art would allegedly arrive at the concentrations recited in claims 41-45 empirically. Page 5, first paragraph of the February 18, 2011 Final Office Action.

Appellants fail to see that the use of safe and effective amounts of antiperspirant active ingredient and mandelic acid (if used together) in a composition according to GUSKEY would automatically result in concentrations within the ranges recited in

claims 41-45. It further has to be taken into account here that the ratio of these components and water together additionally would have to result in gelling. GUSKEY is completely silent in this regard.

Claim 47 (which depends from claim 34) and claim 57 (which depends from claim 56, which in turn depends from claim 55) both recite that the formulation recited in the base claim has a defined yield point. Claim 48 recites that the formulation of claim 34 is present as a hydrogel. Appellants note that in this regard the Examiner alleges that "the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component", and essentially appears to argue that in view thereof the properties recited in claims 47, 48 and 57 are allegedly inherent in the compositions of GUSKEY. See paragraph bridging pages 5 and 6 of the February 18, 2011 Final Office Action.

Appellants submit that it is not seen that "the prior art appears to contain the exact same ingredients", let alone in ratios which result in the formation of a gel. In this regard, it is pointed out that the instant independent claims make it clear that not each and every ratio of components (a), (b) and (c) results in the formation of a gel (otherwise the passage "(a), (b) and (c) being present in ratios which result in gelling" recited in these claims would be redundant).

Claim 49 recites, *inter alia*, that the antiperspirant formulation claimed therein is free from zirconium containing antiperspirant active ingredients.

GUSKEY neither teaches nor suggests that antiperspirant containing compositions should be free of zirconium. On the contrary, several zirconium compounds are expressly mentioned in col. 7, lines 30-47 of GUSKEY as examples of antiperspirant actives which can be used in the compositions taught therein. BHAKOO and HEI are apparently unable to cure this deficiency of GUSKEY (both documents are not concerned with antiperspirants).

VIII. CONCLUSION

Appellants respectfully submit that for at least all of the foregoing reasons, the Examiner has failed to establish that the subject matter of any of the instant claims is anticipated by WILLIAMS and also has failed to establish a *prima facie* case of obviousness of the subject matter of any of claims 34-57 over GUSKEY, BHAKOO and HEI. The Board is, therefore, respectfully requested to reverse the Final Rejection, and to allow the application to issue in its present form.

Respectfully submitted,
Ulrike SCHULZ et al.

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CLAIMS APPENDIX

34. A cosmetic or dermatological formulation, wherein the formulation is transparent and comprises (a) at least one antiperspirant active ingredient, (b) mandelic acid and (c) water, (a), (b) and (c) being present in ratios which result in gelling.

35. The formulation of claim 34, wherein (a) comprises at least one aluminum salt.

36. The formulation of claim 35, wherein (a) comprises aluminum chlorohydrate.

37. The formulation of claim 34, wherein (a) comprises at least one aluminum zirconium salt.

38. The formulation of claim 34, wherein a ratio (a) : (b) is from 15 : 1 to 1 : 1.

39. The formulation of claim 38, wherein the ratio is from 12 : 1 to 2 : 1.

40. The formulation of claim 38, wherein the ratio is from 10 : 1 to 2.5 : 1.

41. The formulation of claim 34, wherein the formulation comprises (a) in an amount of from 1% to 35% by weight, based on a total weight of the formulation.

42. The formulation of claim 41, wherein the formulation comprises (a) in an amount of from 1% to 25% by weight.

43. The formulation of claim 41, wherein the formulation comprises (a) in an amount of from 1% to 20% by weight.

44. The formulation of claim 34, wherein the formulation comprises (b) in an amount of from 0.1% to 10% by weight, based on a total weight of the formulation.

45. The formulation of claim 44, wherein the formulation comprises (b) in an amount of from 0.1% to 8% by weight.

46. The formulation of claim 34, wherein the formulation further comprises a deodorant active ingredient.

47. The formulation of claim 34, wherein the formulation has a defined yield point.

48. The formulation of claim 34, wherein the formulation is present as a hydrogel.

49. A cosmetic or dermatological antiperspirant formulation, wherein the formulation is free from zirconium containing antiperspirant active ingredients and transparent and comprises (a) an antiperspirant active ingredient which comprises one or more aluminum salts, (b) at least one α-hydroxycarboxylic acid and (c) water, (a), (b) and (c) being present in ratios which result in gelling.

50. The formulation of claim 49, wherein (a) comprises aluminum chlorohydrate.

51. The formulation of claim 49, wherein (a) consists of aluminum chlorohydrate.

52. The formulation of claim 49, wherein (b) comprises mandelic acid.

53. The formulation of claim 49, wherein the formulation comprises (a) in an amount of from 1% to 25% by weight and (b) in an amount of from 0.1% to 10% by weight, each based on a total weight of the formulation.

54. The formulation of claim 49, wherein a ratio (a) : (b) is from 10 : 1 to 2.5 : 1.

55. A cosmetic or dermatological antiperspirant formulation, wherein the formulation is transparent and suitable for application to human skin and comprises (a) from 1% to 20% by weight of an antiperspirant active ingredient which comprises one or both of an

aluminum salt and an aluminum zirconium salt, (b) from 0.1% to 8% by weight of mandelic acid and (c) water, (a), (b) and (c) being present in ratios which result in gelling.

56. The formulation of claim 55, wherein a ratio (a) : (b) is from 10 : 1 to 2.5 : 1.

57. The formulation of claim 56, wherein the formulation has a defined yield point.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.